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(54) IMPROVEMENTS IN INSTRUMENTS FOR THE MEASUREMENTS OF FOETAL HEART RATE AND INTRAUTERINE PRESSURE

(71) We, NATIONAL RESEARCH DEVELOPMENT CORPORATION, a British Corporation established by Statute, of Kingsgate House, 66/74 Victoria Street, London, SW1., do hereby declare the invention, for which we pray that a patent may be granted to us and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to instruments for the measurement of intrauterine pressure and foetal heart rate. Such instruments are used in medical obstetrics and may also have corresponding veterinary applications.

In accordance with the invention, an instrument for measuring both intrauterine pressure and foetal heart rate comprises a pressure sensitive element, such as a piston or diaphragm, surrounded by a rigid guard ring to be placed, in use, against the abdomen, a portion of the generally convex abdomen to which the instrument is applied being flattened within the guard ring whereby the reaction force of the abdomen against the pressure sensitive element is indicative of the pressure within the abdomen and thus of the intrauterine pressure, and a device of the ultrasonic doppler effect type for measuring the foetal heart rate mounted on the guard ring and arranged to transmit an ultrasonic signal through the pressure sensitive element into the abdomen and to receive the reflected signal which returns along a similar path.

By a device of the ultrasonic doppler effect type is meant a device which is responsive to changes in frequency of an ultrasonic signal upon reflections from a moving object.

The pressure sensitive element is preferably a diaphragm the movement of which, in response to the reaction force from the abdomen, can be sensed either indirectly, by measurement of the pressure in a chamber of which the diaphragm forms one wall, or directly, by mounting one or more strain gauges on the diaphragm. A diaphragm is preferred to a piston because it eliminates the possibility of foreign matter becoming lodged in the annular space between the piston and the guard ring and impeding the free movement of the piston. The diaphragm may be metallic and formed integrally with the guard ring.

If the ultrasound is transmitted through a chamber behind the diaphragm, the chamber should be as transparent as possible to the sound. It may therefore contain a liquid, such as oil, which has an acoustic impedance substantially the same as that of body tissue. Since liquids are only very slightly compressible, the chamber may also contain a bubble of air or gas to allow the diaphragm to move in response to small forces.

The ultrasonic doppler effect type of device for detecting the foetal heart beat functions by transmitting an ultrasonic signal into the abdomen, detecting a signal reflected from the foetal heart, or any tissue moving in step with the foetal heart, the frequency of the detected signal differing from that of the transmitted signal cyclically as the reflecting tissue moves towards and away from the device. The transmitted and reflected signals, after such amplification as may be necessary, are heterodyned to provide a pulsating audio frequency output. This foetal heart beat signal is then electronically processed into a form which may be fed to a suitable indicator such as an instantaneous ratemeter.

The ultrasonic doppler effect device preferably produces a wide angle beam having an included angle of between 15° and 25° for example. This may be achieved by using a transducer having curved piezoelectric elements. However if a standard transducer producing a pencil beam is used, the device may be fitted with a diverging lens which spreads out of the narrow beam. It has been

[*Price 25p*]

found, that the foetal heart or associated moving tissue can be anywhere within the wide angle beam and still reflect sufficient ultrasound back to the device to obtain a usable signal. The instrument can thus be left in place on the abdomen with only limited need of redirection to follow movement of the foetus.

The use of a diverging lens for widening the field of view of the ultrasonic doppler device is applicable to such devices independently of the means for measuring intra-uterine pressure which forms the other feature of the invention.

One instrument constructed in accordance with the present invention is illustrated in the accompanying drawings, in which:—

Figure 1 is a perspective view;

Figure 2 is a circuit diagram of the ancillary equipment for analysing and presenting the signals produced by the instrument;

Figure 3 is a vertical section taken on the line III-III in Figure 1;

Figure 4 is a vertical section taken on the line IV-IV in Figure 3; and,

Figure 5 is a plan of the bottom part of the instrument as seen on the line V-V in Figure 3.

The instrument illustrated in Figures 1, 3, 4 and 5 has a metallic base part formed by an annular guard ring 6 and an integral diaphragm 7. A Perspex (Registered Trade Mark) cover 8 incorporating a semi-cylindrical lens 9, a housing 10, and a cable clamp with a flexible sleeve 11, is bolted to the top of the base by means of a ring of six screws 12. An O-sealing ring 13 is mounted in an annular groove in the upper surface of the guard ring 6 and provides the seal between the base and cover. This seal effectively isolates a chamber 14 formed above the diaphragm 7 and below the lens 9, and an annular space 15 which forms an extension of the chamber. The chamber contains an electrically insulating mineral oil except for a bubble of air which will normally rise and lodge in part of the annular space 15. The chamber is topped up with oil or bled as necessary through apertures normally closed by two diametrically opposed screw threaded nylon plugs 16.

An annular printed circuit board 17 is mounted on a ledge at the inner periphery of the guard ring 6 and forms the base of the annular space 15. The printed circuit is coupled by leads 18 to two pairs of semi-conductor strain gauges 19 mounted on the upper surface of the diaphragm 7. The strain gauges are coupled through the printed circuit to the external ancillary equipment by means of a lead 20 which is supported by the clamp and flexible sleeve 11 before passing into the interior of the instrument.

An ultrasonic doppler effect type of heart beat detector 21, in this case a Sonicaid D205 unit, is inserted downwards into the housing and rests on the top of the Perspex lens 9. The unit 21 is connected to the external ancillary equipment by means of a cable 22. The unit is held in position in the housing 10 by means of a strap 23 which is subsequently fed into position overlying the unit 21 and extending through slots 24 in the sides of the housing 10. In use the instrument will be placed on the patient's abdomen and held in position by means of the strap 23 which is passed around the patient's body and then secured by means of "Velcro" (Registered Trade Mark) or a buckle. The cables 20 and 22 will be led away to the ancillary equipment and power supply which may be mounted on a trolley.

The foetal heart beat detecting function of the instrument operates as follows. The bottom circular face of the unit 21 operates half as a transmitter of an ultrasonic signal and half as a receiver of a reflected signal, the two halves being separated by the diameter parallel to the line of entry of the cable 22 into the unit, that is perpendicular to the axis of the part cylindrical lens 9. The unit 21 produces a pencil beam which is transmitted downwards through the lens 9, the chamber 14, the diaphragm 7, and into the patient's abdomen. The pencil shape of the beam is modified into a fan-shaped beam having an included angle α of approximately 20° by means of the part cylindrical lens 9. This has two advantages. First the wide angle beam is less sensitive to foetal movement and, secondly, the effect of the lens is to attenuate the ultrasonic energy intensity reaching the foetus. The total energy radiated from the transmitter surface of the unit 21 is 25 mW and 6 mW is radiated from the exit surface of the Perspex lens 9. Because of further attenuation resulting from the divergence of the beam and from absorption in the maternal abdominal and uterine walls, the maximum energy intensity reaching the foetus is estimated to be less than 1 mW/cm^2. The unit produces an ultrasonic beam with a frequency of 2MHz and the doppler shift as determined from the reflected received ultrasonic signal resulting from movement of the foetal heart has a frequency spectrum which is centred at approximately 200 Hz. Unwanted absorption of the signal during its passage through the chamber 14 is minimised by the use of an appropriate mineral oil in the chamber 14. Transmission through diaphragm 7 is maximised by making its thickness satisfy the Fabry-Perot condition for constructive interference of rays for which the angle to the axis of the beam is the mean value for the diverging beam as a whole, i.e. the diaphragm has a thickness such that there is constructive interference

of ultrasound among transmitted component rays not having reflections at the diaphragm surfaces and transmitted component rays having small even numbers of reflections at these surfaces. In practice, if the guard ring 6 and diaphragm 7 are made from magnesium alloy, a thickness of approximately 1.6 mm is appropriate to a beam having an included angle of 20°.

The processing of the reflected signal received back by the unit 21 is illustrated in Figure 2. In order to smooth the signal level variations which result from foetal movement and other causes, the first stage of the processing is to pass the signal through an amplifier 25 with an automatic gain control. This provides a substantially constant output for an input amplitude variation of 100:1 (40 decibels). The next stage is a band pass amplifier 26 of the Wien bridge type which is tunable over the range 70 to 2000 Hz, the band width being 50% of the centre frequency. The band pass filter therefore enhances the signal to noise ratio, the noise in this context being, for example, foetal movements at low frequencies and maternal placental blood flow at high frequencies. The tuning facility enables the right frequency to be chosen for each patient. The final stage in the process is a detector and a dead time generator 27. The dead time generator inactivates the detector for a period of 0.3 seconds after an amplitude burst has been detected and effectively overcomes the difficulty of more than one burst in each cardiac cycle above the threshold level. The output of the detector and dead time generator 27 is fed to a ratermeter 28 which is arranged to give an instantaneous reading of beats per minute on a visual meter 29 and/or to control a chart recorder 30 which may be of the moving pen type.

The doppler signal may also be displayed on a long persistance oscilloscope 31 which is fed directly from the band pass amplifier 26. This signal has intrinsic clinical value in addition to its obvious significance in providing direct assurance that the foetal heart is being properly detected.

The function of the instrument to detect intrauterine pressure simultaneously with the measurement of fetal heart rate is as follows. Operating on the known principle of the tocodynamometer the solid guard ring 6 provides a flat annular reference zone on the patient's abdomen and the generally convex part of the abdomen within this area is flattened by the contact with the diaphragm 7. The resulting pressure on the diaphragm 7 is equal to the intrauterine pressure on the inside of the abdomen wall. This pressure on the diaphragm 7 produces a slight deflection of the diaphragm 7 which is detected by the semi-conducting strain gauges 19. The strain gauges 19, which are mounted in perpendicular pairs at diametrically opposed positions are connected in a bridge balancing circuit 31A the output of which representing the deflection of the diaphragm 7 being amplified in an amplifier 32. The amplified signal feeds an instant visual meter 33 and/or the chart recorder 30. The amplifier 32 is adjusted so that the meter 33 gives a full scale deflection at an intrauterine pressure of 50 mm of mercury pressure.

The instrument, that is the part which is strapped to the patient's body, is smaller and lighter and less expensive than currently available instruments providing similar information, particularly in that the foetal heart rate and intrauterine pressure are measureable simultaneously and coaxially. The illustrated instrument has an overall diameter of only 7.5 cm.

WHAT WE CLAIM IS:—

1. An instrument for the measurement of foetal heart rate and intrauterine pressure, the instrument comprising a pressure sensitive element surrounded by a rigid guard ring to be placed, in use, against the abdomen, a portion of the generally convex abdomen to which the instrument is applied being flattened within the guard ring whereby the reaction force of the abdomen against the pressure sensitive element is indicative of the pressure within the abdomen and thus of the intrauterine pressure, and a device of the ultrasonic doppler effect type for measuring the foetal heart rate mounted on the guard ring and arranged to transmit an ultrasonic signal through the pressure sensitive element into the abdomen and to receive the reflected signal which returns along a similar path.

2. An instrument according to claim 1, in which the pressure sensitive element is a diaphragm.

3. An instrument according to claim 2, in which the diaphragm is formed integrally with the guard ring from a metal.

4. An instrument according to claim 2 or claim 3, in which strain gauges are mounted on the inner surface of the diaphragm.

5. An instrument according to any one of claims 2 to 4, wherein a chamber immediately behind the diaphragm is filled with an electrically-insulating mineral oil having an acoustic impedance substantially the same as that of natural body tissue.

6. An instrument according to any one of claims 2 to 5, in which the diaphragm has a thickness such that there is constructive interference of ultrasound among transmitted component rays not having reflections at the diaphragm surfaces and transmitted component rays having small even numbers of reflections at these surfaces.

7. An instrument according to any one of claims 2 to 6, in which a transmitting/receiving head of the ultrasonic doppler effect device is mounted coaxially with the diaphragm.

8. An instrument according to any one of the preceding claims, in which the ultrasonic doppler effect device produces a wide angle ultrasonic beam.

9. An instrument according to claim 8 when dependent on claim 7, in which the wide angle beam is produced by a diverging lens positioned between the transmitting/receiving head and the diaphragm.

10. An instrument according to claim 9, in which the lens is a part-cylindrical lens formed integrally with a cover plate which is bolted to the guard ring and which is formed with a housing which receives the transmitting/receiving head.

11. An instrument according to claim 10, in which the housing has opposed slots in its side walls and a strap passes through the slots over the head to locate the head in the housing, the strap being arranged to encircle a patient's body to secure the instrument to the patient's abdomen.

12. An instrument according to claim 1, substantially as described with reference to Figures 1, 3, 4 and 5 of the accompanying drawings.

13. A system incorporating an instrument according to any one of the preceding claims in conjunction with ancillary equipment for analysing and presenting the foetal heart rate and intrauterine pressure, the equipment including an electronic circuit which is coupled to the transmitting/receiving head and comprises in series an amplifier with automatic gain control for smoothing the signal level variations resulting from foetal movement, a band pass amplifier for enhancing the signal-to-noise ratio, a detector provided with a dead time generator which inactivates the detector for a period following a heart beat, and a rate meter for producing an output signal which represents the heart beat rate.

14. A system according to claim 13, substantially as described with reference to Figure 2 of the accompanying drawings.

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Fig. 1.

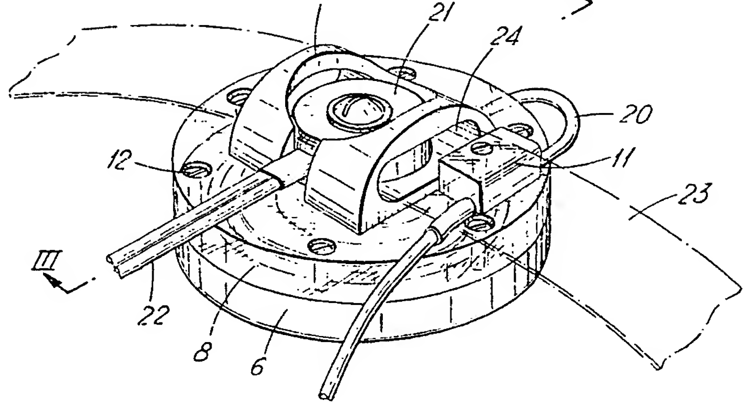

Fig. 2.

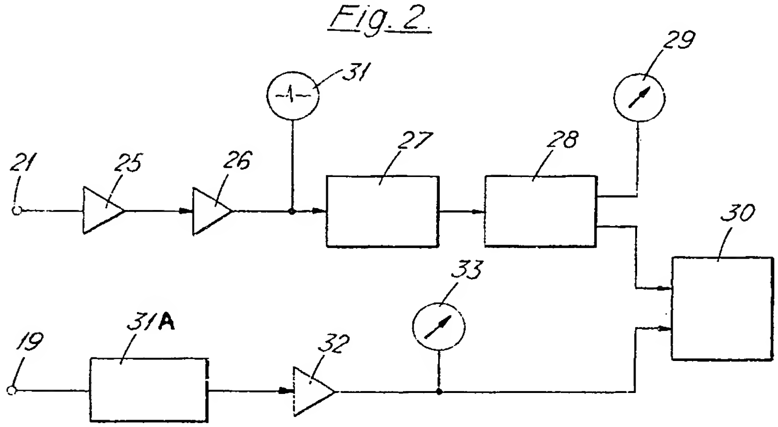

Fig. 3.

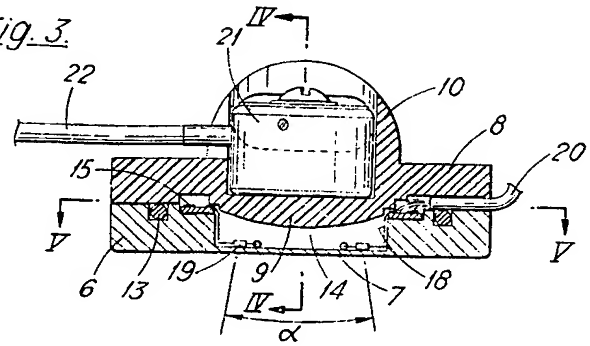

Fig. 4.

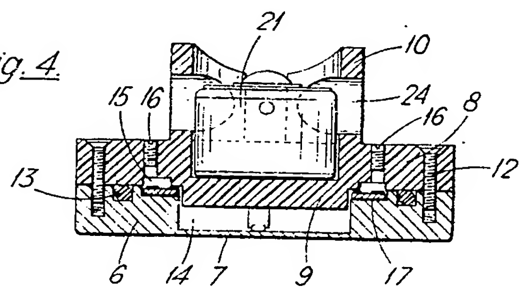

Fig. 5.